

Appl. No. 10/654,228
Att. Docket No. P127C
Amdt. dated December 19, 2006
Reply to Office Action of June 20, 2006
Customer No. 27752

REMARKS

Claim Status

Claims 1-3 are pending in the present application. No additional claims fee is believed to be due. No amendments have been made at this time. Thus, no claim listing is provided herein.

Statutory Double Patenting Under 35 USC §101

Claims 4-6 are rejected under 35 USC §101 as claiming the same invention as that of Claims 1-3 of US Patent 6,641,836. Claims 4-6 have already been canceled by way of a preliminary amendment filed September 3, 2003. Thus, the rejection has been overcome and the Applicants respectfully request that the rejection be withdrawn.

Rejection Under 35 USC §102(e) Over Hart US 6,133,317

Claims 1 and 2 are rejected under 35 US §102(e) as being anticipated by US patent 6,133,317 to Hart (hereinafter "Hart"). The Examiner asserts that the present Claims are directed to a method for enhancing immune response in a dog by feeding the dog a composition including garlic in an amount from about 0.1 weight % to about 1.0 weight % and that Hart discloses a method for improving the immune system of a dog by feeding the dog a dry dog food composition having oxalic acid and/or oxalate in the form of garlic at about 2.2 g/kg.

The Applicants respectfully traverse the rejection. Initially, the Applicant does not find the specific location at which Hart discloses garlic at 2.2g/kg for improving the immune system of a dog. In addition, Hart attempts to disclose every possible amount and use of oxalate and/or oxalic acid for every possible disease or condition ranging from treating tumors, to treating kidney disease, to providing a toothbrush cleaning composition.

Also, Hart himself lists garlic as already being known for containing oxalate. However, Hart provides no teaching that oxalate is responsible for or has any effect on immune response. In addition Hart defines an "effective amount" in numerous,

Appl. No. 10/654,228
Att. Docket No. P127C
Amdt. dated December 19, 2006
Reply to Office Action of June 20, 2006
Customer No. 27752

inconsistent ways. With respect to the claims of Hart, an effective amount is an amount effective to inhibit or reduce tumor growth.

With respect to the Examiner's citations, the Abstract of Hart does not disclose use of oxalate for general immune system health and maintenance. Column 8, lines 24-37 do not disclose any amounts. Column 10, lines 59-62 do disclose amounts, but there is no indication as to whether the amounts are for humans or animals. Column 14, lines 6-10 only discuss treating autoimmune diseases, not general immune system health. Lines 40-46 simply discusses adding oxalate to dog food, giving no amounts or purpose. Column 16 provides an example using oxalate for treating tumors and discloses very high amounts – 1g oxalate per pound of dog food. Column 18 also discloses very high amounts – 500 mg to 2g added to dog food per day. Column 24, lines 18-29, discusses desired blood oxalic acid levels for therapeutic effect against tumors. Column 25, lines 17-20, discusses disease treatment. Column 27, lines 10-18, essentially tries to disclose, with no context or definition, that a proper, balanced diet, including oxalate, maintains health, including the immune system, but does not provide or teach any optimum levels of oxalate for general well-being. Column 28, lines 26-28, as cited by the Examiner, is incomplete. Lines 26-28 cite administration of oxalate before a transplant, yet lines 28-30 indicate that perhaps oxalate should NOT be administered before a transplant. Thus, lines 26-30 taken together disclose nothing meaningful. Lines 45-49 again discuss autoimmune conditions. Column 29, lines 7-8 simply discuss testing urine for oxalate levels in pcts. Lines 40-59 again provide no specific teaching or guidance regarding any amounts of any of the vegetables/plants listed. Column 33, lines 4-18 again only provide vague generalizations with respect to an "effective amount" without defining any such effective amount for treating cancer. Column 38, examples 50-51 again are for treating cancer. Column 39, examples 56 and 61 again are for treating cancer, and use high doses. Column 41, examples again are for treating cancer, but do not provide any guidance with respect to amounts. Column 42, examples 80 and 82 again provide amounts for treating cancer. Column 43, examples 89 and 90 again are directed to autoimmune diseases, and undefined "purifying the blood". Column 45, examples 109 and 110 disclose a method of manufacturing a dog food with high levels of oxalic acid – 1g per pound of food. Finally,

Appl. No. 10/654,228
Atty. Docket No. P127C
Amdt. dated December 19, 2006
Reply to Office Action of June 20, 2006
Customer No. 27752

Column 46, example 115 discloses an undefined "therapeutically effective form" of oxalic acid or oxalate for undefined "maintenance of good pet health".

None of the many cites provided by the examiner would give any one of ordinary skill in the art any idea what an effective amount of garlic would be to be administered to a canine for enhancing immune response in a dog, other than providing a non-lethal dose. The cites listed by the Examiner provide amounts of oxalate or oxalic acid ranging from 0.5 micrograms to 3 grams, in units or dosages anywhere from grams of oxalate per day to grams of oxalate per pound of food.

The only specific reference to garlic and amount of oxalic acid is in Table I wherein it is disclosed that garlic contains 0.36g of oxalic acid per 100 grams of garlic. In addition, Hart starts out discussing oxalate poisoning of his dog and the connection between oxalic acid and kidney failure, concluding that in many cases oxalic acid is lethal. Hart then goes on to describe hundreds of possible, theoretical uses for non-lethal doses of oxalic acid.

However, nowhere does Hart specifically teach the Applicant's claimed 1g to 10g of garlic per kg of diet to enhance immune response in a dog. Hart merely recites almost everything known about oxalic acid, but nowhere does Hart teach specifically effective ranges of garlic to enhance immune response in a dog. Garlic is comprised of many compounds other than oxalic acid. Thus, nowhere does Hart disclose the Applicant's claimed amounts of garlic for enhancing immune response in a dog. Hart does not disclose all of the claim limitations of the present invention. Therefore, the Applicant respectfully requests that the rejection be withdrawn.

Rejection Under 35 USC §102(b) Over Weisman US 5,141,755

Claims 1-3 are rejected under 35 USC §102(b) as being anticipated by US patent 6,141,755 to Weisman (hereinafter "Weisman"). The Examiner asserts that Weisman discloses a dry dogfood composition including garlic in an amount from about 0.001 weight % to about 15 weight % (i.e. from about 0.009 g/kg to about 150 g/kg), protein from about 10 weight % to about 30 weight %, fat from about 4 weight % to about 35 weight %, and fiber from about 2 weight % to about 3 weight %.

Appl. No. 10/654,228
Atty. Docket No. P127C
Amdt. dated December 19, 2006
Reply to Office Action of June 20, 2006
Customer No. 27752

The Applicants respectfully traverse the rejection. Weisman does not disclose compositions containing garlic *at all*, much less garlic in amounts from 0.001 weight % to 15 weight %. The *only* reference to garlic in Weisman is at Column 4, lines 58-59 wherein *imitation garlic flavoring* is disclosed. There is no disclosure with respect to what comprises imitation garlic flavoring. Thus, there is absolutely no garlic disclosed as part of the compositions of Weisman. Therefore, Weisman does not disclose all of the claim limitations of Claims 1-3 and thus can not, by law, anticipate Claims 1-3. Therefore, the rejection can not stand and the Applicant respectfully requests withdrawal of the rejection.

Rejection Under 35 USC §§102(a) and (e) Over Allen US 5,965,153

Claim 1 is rejected under 35 USC §§102 (a) and (e) as being anticipated by US patent 5,965,153 to Allen (hereinafter "Allen"). The Examiner asserts that Allen discloses a method for reducing fungal infections and promoting the health of a dog by feeding a dog a dietary supplement having an effective amount of garlic.

The Applicant respectfully traverses the rejection. Although Allen discloses compositions comprising garlic, those compositions are directed at skin health and preventing unwanted non-seasonal shedding of hair. Allen does not disclose any examples or particular amounts of garlic that would be effective to reduce such non-seasonal shedding, much less disclose use of garlic for immune health. Therefore, Allen does not disclose all of the claim limitations and does not anticipate Claim 1. The Applicant therefore respectfully requests that the rejection be withdrawn.

With respect to the Examiner's citation of *Atlas Powder Co. v. Ireco Inc.*, (hereinafter *Atlas Powder*), and *In re Best* (hereinafter "*Best*"), the compositions at issue are not identical because no "effective amount" amount of garlic is disclosed by Allen – in fact no amounts of garlic are disclosed by Allen. Therefore, because no amounts of garlic are disclosed by Allen, and the purpose of Allen is to reduce shedding, one can not say that an undisclosed amount of garlic "effective" to reduce non-seasonal shedding is a composition identical to that used in the present invention. Thus, the analyses of *Atlas Powder* and *Best* are inapplicable.

Appl. No. 10/654,228
Atty. Docket No. P127C
Amdt. dated December 19, 2006
Reply to Office Action of June 20, 2006
Customer No. 27752

Rejection Under 35 USC §102(a) and (e) Over Lewandowski US 5,976,549

Claim 1 is rejected under 35 USC §§102(a) and (e) as being anticipated by US patent 5,976,549 to Lewandowski (hereinafter "Lewandowski"). The Examiner asserts that Lewandowski discloses a method of reducing fungal infections and promoting the health of a dog by feeding a dog a dietary supplement having an effective amount of garlic.

The Applicants respectfully traverse the rejection. Similar to Allen, above, there are no amounts of garlic disclosed by Lewandowski. The purpose of Lewandowski is to contact the oral tissues with raw garlic to reduce or eliminate bad breath. Thus an "effective amount", which amount is not disclosed, would be an amount effective to reduce bad breath. The Applicant's method enhances immune health. Because Lewandowski does not disclose any actual amounts of garlic, one can not tell or assume that an amount effective to reduce bad breath would be the same as the Applicant's amounts of garlic. Therefore Lewandowski does not disclose all of claim limitations of the Applicant's method and does not anticipate Claim 1.

Similarly to Allen, above, *Atlas Power* and *Best* are inapplicable because the composition of Lewandowski is not identical to that administered as part of the method of the present Claim 1. Lewandowski only discloses an "effective amount" of garlic for reducing or eliminating bad breath, though never disclosing what such an "effective amount" might be, whereas the present invention recites a method for enhancing immune response in a dog comprising the steps of feeding said dog a diet including an effective amount of garlic for a time sufficient for said garlic to be absorbed by said dog. Lewandowski does not disclose the same "effective amount" of garlic because Lewandowski does not disclose any actual amount, and thus does not disclose a composition identical to that of the present invention.

Therefore *Atlas Power* and *Best* are inapplicable, the rejection has been overcome, and the Applicant respectfully requests that the rejection be withdrawn.

Appl. No. 10/654,228
Atty. Docket No. P127C
Amdt. dated December 19, 2006
Reply to Office Action of June 20, 2006
Customer No. 27752

Rejection Under 35 USC §103(a) Over Weisman US 5,141,755

Claims 1-3 are rejected under 35 USC §103(a) as being obvious over Weisman. The Examiner asserts that Weisman does not explicitly teach administering a dry dog food composition to a dog for the specific purpose of enhancing immune response. But, the Examiner asserts that it would have been obvious to administer such a composition for such purpose because by administering such a composition, one would intrinsically enhance the immune response of the dog.

The Applicants respectfully traverse the rejection. Weisman does not in fact disclose *any* garlic. Therefore, the Examiner has not met the burden for establishing a *prima facie* case of obviousness. In order for a *prima facie* case of obviousness to be established, three criteria must be met. First, there must be some suggestion or motivation, i.e. desirability, either in the references themselves, or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references must teach or suggest all of the claim limitations. Furthermore, the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in the Applicant's disclosure. See MPEP § 2143 citing *In Re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir 1991).

Weisman only discloses *imitation* garlic *flavoring*. There is no teaching, suggestion or motivation, and no expectation of success for any purpose, for administering any actual garlic to an animal. Therefore, because Weisman does not use any actual garlic at all, Weisman could not have led one of ordinary skill in the art to use garlic for any purpose.

Furthermore, with respect to the Examiner's citation of *In re Best*, because Weisman does not actually use any garlic, the composition of Weisman can not be identical in structure or composition to that used in the method of the present Claims. Thus, *Best* is inapplicable because the compositions are not identical. Therefore, the

Appl. No. 10/654,228
Atty. Docket No. P127C
Amdt. dated December 19, 2006
Reply to Office Action of June 20, 2006
Customer No. 27752

rejection can not stand and the Applicant respectfully requests withdrawal of the rejection.

Rejection Under 35 USC §103(a) Over Allen US 5,965,153

Claim 1 is rejected under 35 USC §103(a) as being obvious over Allen. The Examiner asserts that Allen does not specifically teach a method of feeding a dietary supplement containing garlic to a dog for enhancing immune response of the dog, but that by feeding such a composition to a dog, one would intrinsically enhance the dog's immune response.

The Applicants respectfully traverse the rejection. The Examiner has not met the burden for establishing a *prima facie* case of obviousness. In order for a *prima facie* case of obviousness to be established, three criteria must be met. First, there must be some suggestion or motivation, i.e. desirability, either in the references themselves, or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references must teach or suggest all of the claim limitations. Furthermore, the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in the Applicant's disclosure. See MPEP § 2143 citing *In Re Vaack*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir 1991).

Allen does not disclose *any* actual amount of garlic. Thus, Allen does not provide any definition for what an "effective amount" of garlic might be, even for Allen's stated purpose of reducing non-seasonal shedding. Because Allen does not provide one of skill in the art with any indication of what an "effective amount" of garlic might be to prevent shedding, Allen also could not have led one of skill in the art to what an effective amount of garlic would be for enhancing immune response. It is not necessarily the case that by feeding an amount of garlic effective to reduce shedding one would intrinsically enhance the immune system. For example, see all of the conflicting disclosure in Hart regarding oxalic acid – an amount effective for killing tumor cells can also cause kidney failure. Therefore, there is no teaching, suggestion or motivation in Allen to add any particular

Appl. No. 10/654,228
Atty. Docket No. P127C
Amdt. dated December 19, 2006
Reply to Office Action of June 20, 2006
Customer No. 27752

amount of garlic, or even to use garlic at all, for enhancing immune response. Thus, there is also no expectation of success because one would not have been taught by Allen to use garlic at all, nor what amount, for enhancing immune response. Finally, because there is no indication whatsoever of any range of amount of garlic provided, there is no way to determine or conclude that Allen discloses all of the claim limitations.

In addition, the Examiner again cites *Best*, asserting that when compositions are identical, a *prima facie* case of either anticipation or obviousness has been established. Allen does not disclose or suggest what an effective amount of garlic for curbing shedding might be. There is no amount of garlic given in Allen, thus, one has no idea if the compositions are identical. There is no context from which to even begin to determine if the compositions are identical. Therefore, Allen's unsupported, uncontextualized disclosure of an "effective amount" for reducing non-seasonal shedding could not have led one of skill in the art to the Applicant's method. Because one can not conclude that the compositions are identical, *Best* is inapplicable.

Therefore, the rejection has been overcome and the Applicant respectfully requests that the rejection be withdrawn.

Rejection Under 35 USC §103(a) Over Lewandowski US 5,976,549

Claims 1 and 2 are rejected under 35 USC §103(a) as being obvious over Lewandowski. The Examiner asserts that Lewandowski does not explicitly teach a method of feeding garlic coated/impregnated food to a dog for the specific purpose of enhancing immune response, or the specific weight percentages of garlic as recited in the present claims, but that it would have been obvious to one of skill in the art to adjust the percentage of garlic, and that when such a composition were fed to a dog, one would intrinsically enhance the dog's immune response.

The Applicants respectfully traverse the rejection. The Examiner has not met the burden for establishing a *prima facie* case of obviousness. In order for a *prima facie* case of obviousness to be established, three criteria must be met. First, there must be some suggestion or motivation, i.e. desirability, either in the references themselves, or in the knowledge generally available to one of ordinary skill in the art, to modify the reference

Appl. No. 10/654,228
Atty. Docket No. P127C
Amdt. dated December 19, 2006
Reply to Office Action of June 20, 2006
Customer No. 27752

or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references must teach or suggest all of the claim limitations. Furthermore, the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in the Applicant's disclosure. See MPEP § 2143 citing *In Re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir 1991).

In the instant case, as with *Allen*, above, *no* amounts, percentages, or ranges of garlic are disclosed by Lewandowski. Therefore, there is no teaching, suggestion or motivation to use any particular amount of garlic, and thus no expectation of success for using any particular amount of garlic for any reason. In addition, because no amount of garlic is given in Lewandowski, even for the purpose of eliminating bad breath, one can not conclude that Lewandowski discloses all of the claim limitations of a method for enhancing immune response. Thus, all the claim limitations are not disclosed.

In addition, the Examiner cites *In re Aller*, (hereinafter "*Aller*"), for the proposition that arriving at an effective amount of garlic for enhancing immune response would simply be a matter of routine experimentation and optimization. However, Lewandowski provides no basis or context from which one of skill in the art could even begin any routine experimentation. One would have to begin experimenting with no suggestion even of a starting point. Therefore, because no amounts of garlic are disclosed at all in Lewandowski, arriving at the composition of the presently claimed method would involve far more than routine experimentation or optimization. From the teaching of Lewandowski one could not have even concluded that any amount of garlic would be effective to enhance immune response.

Furthermore, with respect to the Examiner's citation of *Best*, because no amounts of garlic are disclosed by Lewandowski, one can not possibly determine if the compositions are identical. The amounts of garlic useful for reducing or eliminating bad breath may not be the same as those useful for enhancing the immune system. However, because Lewandowski provides no amounts, one can not determine or conclude that the compositions are identical and therefore *Best* is inapplicable.

Appl. No. 10/654,228
Atty. Docket No. P127C
Amdt. dated December 19, 2006
Reply to Office Action of June 20, 2006
Customer No. 27752

Therefore, the rejection has been overcome and the Applicant respectfully requests that the rejection be withdrawn.

Rejection Under 35 USC §103(a) Over Shields US 6,156,355

Claims 1-3 are rejected under 35 USC §103(a) as being obvious over US patent 6,156,355 to Shields (hereinafter "Shields"). The Examiner asserts that Shields does not explicitly teach the specific purpose of enhancing immune response, or the claimed amount of garlic, but that it would have been obvious to one of skill in the art to adjust the percentage of garlic, and that when such a composition were fed to a dog, one would intrinsically enhance the dog's immune response.

The Applicants respectfully traverse the rejection. The Examiner has not met the burden for establishing a *prima facie* case of obviousness. In order for a *prima facie* case of obviousness to be established, three criteria must be met. First, there must be some suggestion or motivation, i.e. desirability, either in the references themselves, or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references must teach or suggest all of the claim limitations. Furthermore, the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in the Applicant's disclosure. See MPEP § 2143 citing *In Re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir 1991).

As with Allen and Lewandowski, Shields does not provide any amounts or ranges of garlic in any of the compositions. Thus, there is no teaching, suggestion or motivation to use any particular amounts of garlic at all, and no expectation of success for any particular amount of garlic. There is also no expectation of success for using garlic to enhance immune response because Shields provides only limited disclosure regarding garlic used for its antioxidant activity, cardiac benefits and inhibition of growth of pathogenic organisms. Finally, because no amounts, percentages or ranges of garlic are disclosed in Shields, Shields does not disclose all of the claim limitations.

Appl. No. 10/654,228
Atty. Docket No. P127C
Amdt. dated December 19, 2006
Reply to Office Action of June 20, 2006
Customer No. 27752

In addition, with respect to *Aller*, because Shields provides no amount of garlic to even use as a starting point for experimentation or optimization. Figuring out what amount, if any, would be effective to enhance immune response would not simply be a matter of routine experimentation. Again, one would have had to start from scratch, and one can not "optimize" or adjust an amount one is not given.

Finally, *Best* is also not applicable. Because there is no way whatsoever, from the disclosure of Shields, to determine what the composition of Shields actually is, one can not conclude that the compositions of Shields and the present invention are identical. Thus, one can not conclude that the undefined amounts of garlic disclosed in Shields would intrinsically enhance the immune system.

Therefore, the rejection has been overcome and the Applicant respectfully requests withdrawal of the rejection.

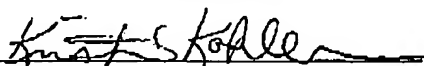
Conclusion

In light of the above remarks and amendments, it is requested that the Examiner reconsider and withdraw the rejections. Early and favorable action in the case is respectfully requested.

This response represents an earnest effort to place the application in proper form and to distinguish the invention as now claimed from the applied documents. In view of the foregoing, reconsideration of this application and the arguments presented herein, and allowance of all pending Claims is respectfully requested.

Respectfully submitted,

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Date: December 19, 2006
Customer No. 27752